BOARD BRIEFS

A publication of the Board of Medicine for licensed and certified practitioners in Virginia

Newsletter #54

Spring 199

Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain

All practitioners with the authority to prescribe controlled substances Schedule II-V must have a clear understanding of their obligations and responsibilities when using these agents. As the medical community promotes the new advances in the management of the patient with chronic pain, all practitioners must understand not only that the use of opioids is an important part of the armamentarium for managing the chronic pain patient, but also that opioids must be prescribed, dispensed and administered in good faith for accepted medicinal or therapeutic purposes.

The Code of Virginia permits the use of opioids in large amounts for patients with intractable pain. The Drug Control Act, Virginia Code § 54.1-3408.1 states, *"In the case of a patient with intractable pain, the attending physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be deemed to be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes. Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this section."*

In 1995, § 54.1-2971.01 was added to the Medical Practice Act:

"A. Consistent with § 54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and § 54.1-3408.1 shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes.

B. The Board of Medicine shall advise physicians of the provisions of this section and § 54.1-3408.1."

In 1997, the Medical Society of Virginia, at the request of the Joint Subcommittee of the General Assembly, appointed a special committee to develop a guideline document to meet the needs of physicians in the Commonwealth regarding the prescribing of opioids for chronic, noncancer pain management. These guidelines were passed by the House of Delegates of the Medical Society during an annual meeting in November 1997.

The Virginia Board of Medicine welcomes these guidelines. These guidelines, although they do not carry the weight of law or regulation, will be of help to those who treat pain patients as to the proper use of opioids and the documentation required.

Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain

For the purpose of this document the following terms shall have the following definitions:

***Addiction** is a disease process involving the use of opioid(s) wherein there is a loss of control, compulsive use, and continued use despite adverse social, physical, psychological, occupational, or economic consequences.*

***Substance abuse** is use of any substance(s) for nontherapeutic purposes; or use of medication for purposes other than those for which it is prescribed.*

***Physical dependence** is a physiologic state of adaptation to a specific opioid(s) characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is a predictable sequelae of regular, legitimate opioid or benzodiazepine use, and does not equate with addiction.*

***Tolerance** is a state resulting from regular use of opioid(s) in which an increased dose of the substance is needed to produce the desired effect. Tolerance may be a predictable sequelae of opiate use and does not imply addiction.*

***Withdrawal syndrome** is a specific constellation of signs and symptoms due to the abrupt cessation of, or reduction in, a*

regularly administered dose of opioid(s). Opioid withdrawal is characterized by three or more of the following symptoms that develop within hours to several days after abrupt cessation of the substance: (a) dysphoric mood, (b) nausea and vomiting, (c) muscle aches and abdominal cramps, (d) lacrimation or rhinorrhea, (e) pupillary dilation, piloerection, or sweating, (f) diarrhea, (g) yawning, (h) fever, (i) insomnia.

Acute pain is the normal predicted physiological response to an adverse (noxious) chemical, thermal, or mechanical stimulus. Acute pain is generally time limited and is historically responsive to opioid therapy, among other therapies.

Chronic Pain is persistent or episodic pain of a duration or intensity that adversely affects the function or well-being of the patient, attributable to any nonmalignant etiology.

Co-Assessment, Documentation and Treatment

A. History and Physical Examination

The physician must conduct a complete history and physical exam of the patient prior to the initiation of opioids. At a minimum, the medical record must contain documentation of the following history from the chronic pain patient:

1. *Current and past medical, surgical, and pain history including any past interventions and treatments for the particular pain condition being treated.*
2. *Psychiatric history and current treatment.*
3. *History of substance abuse and treatment*
4. *Pertinent physical examination and appropriate diagnostic testing.*
5. *Documentation of current and prior medication management for the pain condition, including types of pain medications, frequency with which medications are/were taken, history of prescribers (if possible), reactions to medications, and reasons for failure of medications.*
6. *Social/work history.*

B. Assessment

A justification for initiation and maintenance of opioid therapy must include at a minimum the following initial workup of the patient:

1. *The working diagnosis (or diagnoses) and diagnostic techniques. The original differential diagnosis may be modified to one or more diagnoses.*
2. *Medical indications for the treatment of the patient with opioid therapy. These should include, for example, previously tried (but unsuccessful) modalities/medication regimens, diverse reactions to prior treatments, and othe rationale for the approach to be utilized.*
3. *Updates on the patient's status including physical examination data must be periodically reviewed, revised, and entered in the patient's record.*

C. Treatment Plan and Objectives

The physician must keep detailed records on all patients, which at a minimum include:

1. *A documented treatment plan.*
2. *Types of medication(s) prescribed, reason(s) for selection, dose, schedule administered and quantity.*
3. *Measurable objectives such as:*
   a. *Social functioning and changes therein due to opioid therapy.*
   b. *Activities of daily living and changes therein due to opioid therapy.*
   c. *Adequacy of pain control using standard pain rating scale(s) or at least statements of the patient's satisfaction with the degree of pain control.*

D. Informed Consent and Written Agreement for Opioid Treatment

Written documentation of both physician and patient responsibilities must include:

1. *Risks and complications associated with treatment using opioids.*
2. *Use of a single prescriber for all pain related medications.*
3. *Use of a single pharmacy, if possible.*
4. *Monitoring compliance of treatment;*
   a. *Urine/serum medication levels screening (including checks for nonprescribed medications/substances) when requested.*
   b. *Number and frequency of all prescription refills.*
   c. *Reason(s) for which opioid therapy may be discontinued (e.g. violation of written agreement item(s)).*

E. Periodic Review

Intermittent review and comparison of previous documentation with the current medical records are necessary to determi if continued opioid treatment is the best option for a patient. Each of the following must be documented at every office visit:

1. *Efficacy of Treatment*
   a. *Subjective pain rating (e.g. 0-10 verbal assessment of pain)*
   b. *Functional changes.*
      i. *Improvement in ability to perform activities of daily living (ADLs)*
      ii. *Improvement in home, work, community or social live.*
2. *Medication side effects.*
3. *Review of the diagnosis and treatment plan.*
4. *Assessment of compliance (e.g. counting pills, keeping record of number of medication refills, frequency of refills and disposal of unused medications/prescriptions).*
5. *Unannounced urine/serum drug screens and indicated laboratory testing, when appropriate.*

F. Consultation

Most chronic noncancer patients, like their cancer pain counterparts can be adequately and safely managed by most physicians without regard for specialty. However, the treating physician must be cognizant of the availability of pain management specialists to whom the complex patient may be referred. The physician must be willing to refer the patient to a physician or a center with more expertise when indicated or when difficult issues arise. Consultations must be documented. The purpose of this referral should not necessarily be to prescribe the patient opoids.

G. Medical Records

Accurate medical records must be kept, including, but not limited to documentation of:

1. *All patient office visits and other consultations obtained.*
2. *All prescriptions written, including date, type(s) of medication, and number (quantity) prescribed.*
3. *All therapeutic and diagnostic procedures performed.*
4. *All laboratory results.*
5. *All written patient instructions and written agreements.*

A licensed practitioner who prescribes opioids in the Commonwealth of Virginia does not need a license from the Virginia Board of Pharmacy, but he must have a valid controlled substance registration from the Drug Enforcement Agency of the United States Department of Justice.